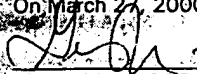


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On March 27, 2000

  
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3/27/2000  
Date of  
Signature

**PATENT**  
#99-0134-UNI  
Case #F7469(V)

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: De Boer et al.  
Serial No.: 09/454,774  
Filed: December 3, 1999  
For: FOOD COMPOSITION

Edgewater, New Jersey 07020  
March 27, 2000

**SUBMISSION OF PRIORITY DOCUMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Pursuant to rule 55(b) of the Rules of Practice in Patent Cases, Applicants are submitting herewith certified copy of the European Application No. 98204419.0, filed on December 22, 1998, upon which the claim for priority under 35 U.S.C. § 119 was made in the United States.

It is respectfully requested that the priority document be made part of the file history.

Respectfully submitted,



Gerard J. McGowan, Jr.  
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**Bescheinigung**

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The attached documents  
are exact copies of the  
European patent application  
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**Patentanmeldung Nr. Patent application No. Demande de brevet n°**

**98204419.0**

Der Präsident des Europäischen Patentamts;  
Im Auftrag

For the President of the European Patent Office

Le Président de l'Office européen des brevets  
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**Blatt 2 der Bescheinigung**  
**Sheet 2 of the certificate**  
**Page 2 de l'attestation**

Anmeldung Nr.:  
Application no.: 98204419.0  
Demande n°:

Anmeldetag:  
Date of filing: 22/12/98  
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Anmelder:  
Applicant(s):  
Demandeur(s):  
**UNILEVER N.V.**  
**3000 DK Rotterdam**  
**NETHERLANDS**

Bezeichnung der Erfindung:  
Title of the invention:  
Titre de l'invention:  
**Food composition**

In Anspruch genommene Priorität(en) / Priority(ies) claimed / Priorité(s) revendiquée(s)

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Am Anmeldetag benannte Vertragsstaaten:  
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**FOOD COMPOSITION****Field of the invention**

- 5 The present invention relates to an edible composition containing both (plant) sterols (and/or sterol-containing compounds) as well as carotenoids.

**Background of the invention**

- 10 Various plant sterols and plant sterol derived compounds have (when consumed in the right form) a known and well-documented effect on blood cholesterol level. Among these are compounds like  $\beta$ -sitosterol, the hydrogenated form  
15 thereof ( $\beta$ -sitostanol), as well as esterified forms thereof. Sterols have been reported to be capable of lowering the level of blood cholesterol (Pollak & Kritchevsky, Monographs in Atherosclerosis, 1981). In particular, the group of 4-desmethylsterols, 4-  
20 monomethylsterols, their hydrogenated forms and fatty acid esters have been reported to have a beneficial effect on blood cholesterol level, in particular on LDL-cholesterol.
- 25 Compounds belonging to the class of carotenoids are best known for their role as dietary antioxidants, although other potentially protective mechanisms for this group of compounds have been identified e.g. provitamin A activity, role in immunity and cell-cell communication. About 600 carotenoids occur in nature of which the six major ones in  
30 the diet are  $\beta$ -carotene, lycopene, lutein,  $\beta$ -cryptoxanthin,  $\alpha$ -carotene and zeaxanthin. Although no thorough scientific base for claiming a direct relation between cause and effect of the carotenoid intake and disease incidence has been proven thusfar, inverse  
35 associations between carotenoid intake or status and disease incidence have been found.

- Hence, when it is desired to achieve a lowering of blood cholesterol level, an increased intake of the sterol  
40 compounds as defined above may be desired. However, a disadvantage with the use of such compounds is that the absorption of lipophilic micronutrients, such as  $\beta$ -carotene and lycopene may decrease. It has been found that sterol-containing compositions (which include such micro-nutrients  
45 like  $\beta$ -carotene) do not result in a measurable increase in carotenoid level in the blood serum.

**Summary of the invention**

- 50 The current invention provides a solution to such problems, by which the blood cholesterol effect of the sterols is

obtained together with an (increased) bioavailability of carotenoids such as  $\beta$ -carotene,  $\alpha$ -carotene, lycopene, lutein,  $\beta$ -cryptoxanthin or mixtures thereof (as measured e.g. by a post-prandial clinical trial).

5 It has now been found that the above may be achieved by an edible composition comprising (phyto) sterols or derivatives thereof in an amount of at least 0.5 (g) (preferably at least 1.5 (g), more preferably at least 2 (g)) per serving, further comprising carotenoids in an amount of at least 1 (mg) (preferably at least 2 (mg)) per serving, and wherein at least 20% wt of the carotenoids is in another phase than the majority of the (phyto) sterols or derivatives thereof. Preferably, the majority of the carotenoids is in another phase than the majority of the (phyto) sterols or derivatives thereof. As an example of "another phase", part of the carotenoids may be present in the compositions according to the invention in an extended water phase, e.g. in particulates of vegetable origin, the sterols being present as (part of) a fat phase, e.g. dissolved in the fat, or emulsified in the fat phase. "Majority of ..." in this respect is herein to be understood as "at least 50% by weight of the total amount of ... in the composition per serving".

25 In the above composition, the carotenoids include preferably  $\beta$ -carotene, lycopene, lutein,  $\beta$ -cryptoxanthin,  $\alpha$ -carotene, zeaxanthin or mixtures thereof, as these are among the more hydrophobic carotenoids (with  $\beta$ -carotene and lycopene being most lipophilic), and the effect of the present invention on bioavailability will be most distinct. Even more preferred in the compositions according to the invention is the presence of  $\beta$ -carotene and lycopene in weight ratio of  $\beta$ -carotene:lycopene of between 1:20 and 1:0.2, more preferably between 1:10 and 1:0.1. It is also preferred that at least the majority of the carotenoids in the compositions according to the invention are  $\beta$ -carotene, lycopene or mixtures thereof.

40 A convenient way to achieve the desired amount of carotenoids is present in another phase, is to prepare a composition wherein at least 20% wt (preferably at least 50% wt%) of the total amount of carotenoids is included in the composition in the form of (partly broken up) chromoplasts and/or chloroplasts. Chromoplasts and chloroplasts are microstructures that can be found in cells of vegetable matter by nature. Chromo- and/or chloroplasts of a number of fruit and vegetable species contain carotenoids, in various quantities and compositions. In particular tomatoes are rich in lycopene (predominantly in



red tomatoes) and  $\beta$ -carotene (predominantly in orange tomatoes), located to a large extent in chromoplasts. Another good source of  $\beta$ -carotene is carrots.

5 The above can be achieved conveniently if at least the majority of the carotenoids are present in intact or only partly disrupted chromoplasts or chloroplasts, while at the same time tissue structures of vegetable matter are still relatively intact i.e. recognizable fruit or vegetable  
10 particulates, whole cells containing chromo- and/or chloroplasts. This can be achieved by product formulations containing ingredients such as tomatoes (red, yellow or orange), peppers (including sweet peppers in colors red, yellow, orange, red (hot) peppers), water mellow, carrots,  
15 pink grapefruit, or other good sources of (particularly but not exclusively) the hydrophobic carotenoids  $\beta$ -carotene and lycopene. It is most preferred if the compositions according to the invention comprise chunks or pieces of said fruit and vegetables.

20 Preferably, the content of  $\beta$ -carotene and/or lycopene, in the presence of plant sterols (or derivatives thereof), in the compositions according to the invention is such that a significant (i.e. having a statistical significance)  
25 absorption of these carotenoids can be shown. This can be determined by a so called post-prandial clinical trial, in which chylomicron-rich fractions - that are isolated from blood samples taken up to 8 or 12 hours after consumption of a meal - are analysed for their carotenoid contents.

30

#### Detailed description of the invention

35 Preferably, the amount of (plant) sterols and carotenoids in the composition is such that levels of carotenoids in the body are increased and the level of (serum) blood cholesterol, and LDL-cholesterol in particular, are decreased, when such composition is ingested regularly, for a period of at least 14 days.

40

As various vegetables and fruits like tomatoes are suitable sources of carotenoid-containing chromo- and/or chloroplasts, these are preferred sources for the carotenoids. Following this, a composition according to the  
45 invention may be a food composition comprising tomatoes, such as e.g. an Italian-style sauce to go with pasta, with added to the sauce (phyto) sterols or derivatives thereof in such an amount that per serving at least 0.5 (g), preferably at least 1.5 (g) of (phyto)sterol or derivative  
50 thereof is ingested. Such a sauce may be anything from a very smooth, more or less homogeneous mixture, to a thick sauce containing chunks of tomato or other fruit or

vegetable, depending on desired end result and processing. Even more preferred in the above are levels of at least 2 or even 3 (g) (phyto)sterol or derivative thereof (per serving).

5 The size and weight of a serving will depend on the type of the food product, but will be about the size/weight of that food product as is usually consumed by the average adult person. For Italian-type tomato sauces for pasta dishes  
10 such a serving may be about 150-100 gram.

Also depending on processing, at least part of the carotenoid-containing chromoplasts and/or chloroplasts is presumably present as a part of plant cells.

15 Also suitable to provide at least part of the composition according to the invention are (besides various colored tomatoes): sweet peppers (red, yellow or orange), red (hot) peppers, water mellow, carrots, pink grapefruit, or other  
20 fruit or vegetable containing carotenoids. The compositions according to the invention may comprise from 10-99% by weight of these fruit or vegetables. Also, extracts of these fruit and vegetables may be used to provide such carotenoids. In that case, the compositions according to  
25 the invention may comprise less than 10% wt of the fruit and vegetables. Furthermore it is possible to use synthetic sources of carotenoids.

In processing the fruit or vegetables to make them suitable for incorporation in the compositions according to the invention a temperature treatment may be applied (besides other processing steps). The carotenoid sources may be heat-treated in order to achieve a partial disruption of the chromo- and chloroplast structures while at the same  
30 time recognizable tissue structures are still present.

The fruit or vegetables mentioned may be subjected to pretreatment like washing, cutting, heating, cooking, etcetera, but not extensive homogenization, as this may  
40 destroy the chromo- and chloroplasts too much.

An advantage of the above is that the carotenoids that are ingested are carotenoids of natural sources which are abundantly available, such as in tomatoes. Also, the  
45 compositions according to the invention may be made in the form of e.g. standard tomato sauces for e.g. Italian-style pasta dishes, which have a universal, natural and healthy appeal.

50 Additionally, the compositions according to the invention are preferably low in fat. (Fat is herein to be understood as to comprise all fatty acid triglycerides such as

vegetable oils.) Preferably, the composition should contain less than 10% of fat.

5 The invention further relates to a process for preparing the compositions as described above. This can be a process for the preparation of a food product which process comprises (not necessarily in the order given) at least the steps of:

- 10 - comminuting of carotenoid-containing fruit or vegetables,  
- heating the carotenoid-containing fruit or vegetables,  
- mixing the carotenoid-containing fruit or vegetables with a (plant) sterol or derivative thereof.

15 Preferably in the above process, said carotenoid-containing fruit- or vegetables comprise tomato, capsicum (red, yellow or orange), red peppers, water mellow, carrots, pink grapefruit or mixtures thereof. Preferably, the fruit or vegetables to make up the composition according to the invention are chosen such that the weight ratio of (plant)  
20 sterols or derivatives thereof : carotenoids in the final composition is between 100:1 and 10000:1. (more preferably between 250:1 and 4000:1).

25 In the present invention, (phyto) sterols are herein to be understood to comprise also derivatives of these compounds, such as esters. Preferred in this respect are  $\beta$ -sitostanol,  $\beta$ -sitosterol, and esters thereof with e.g. fatty acids (to yield e.g.  $\beta$ -sitosteryl linoleate).

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**Claims**

1. Edible composition comprising (phyto) sterols or derivatives thereof in an amount of at least 0.5 (g) per serving, further comprising carotenoids in an amount of at least 1 (mg) per serving, and wherein at least 20% wt of the carotenoids is in another phase than the majority of the (phyto) sterols.
2. Composition according to claim 1, wherein the majority of the carotenoids (at least 50% wt) is in another phase than the majority of the (phyto) sterols.
3. Composition according to claim 1 or 2, comprising (phyto) sterols in an amount of at least 1.5 (g) per serving.
4. Composition according to claim 1-3, comprising carotenoids in an amount of at least 2 (mg).
5. Composition according to claim 1-4, wherein the carotenoids are selected from the group consisting of  $\alpha$ -carotene,  $\beta$ -carotene, lycopene or mixtures thereof.
6. Composition according to any of claims 1-5, wherein the carotenoids comprises  $\beta$ -carotene and lycopene in a ratio of between 1:20 and 1:0.2.
7. Composition according to claim 1-6, wherein at least 20% wt of the carotenoids is present in the form of (partly broken up) chromoplasts and/or chloroplasts.
8. Composition according to claim 7, wherein the majority (at least 50% wt) of the carotenoids is present in the form of (partly broken up) chromoplasts and/or chloroplasts.
9. Composition according to claim 7 or 8, wherein at least part of the chromoplasts and/or chloroplasts are present as a part of (intact) plant cells.
10. Composition according to claim 1-9, wherein at least part of the carotenoids are obtained from tomato, (sweet) peppers (red, yellow or orange), red (hot) peppers, water mellon, carrots, pink grapefruit, or other fruit or vegetable containing carotenoids.
11. Composition according to claim 10, wherein at least part of the carotenoid-containing fruit or vegetable has been subjected to extensive heat treatment (temperatures above 70°C).

12. Composition according to claim 1-11, which comprises (extracts of) processed tomato, capsicum, red peppers, water mellon, carrots, or other fruit or vegetables containing carotenoids, in an amount of 10-99%, based on fresh weight.
13. Composition according to claim 1-12, in the form of a sauce, paste, puree or juice.
14. Process for the preparation of a food product which process comprises (not necessarily in the order given) at least the steps of:
- comminuting to pieces of carotenoid-containing fruit or vegetables,
  - heating the carotenoid-containing fruit or vegetables,
  - mixing the carotenoid-containing fruit or vegetables with a (plant) sterol or derivative thereof.
15. Process according to claim 14, wherein the carotenoid containing fruit or vegetables comprise tomato, (sweet) pepper (red, yellow or orange), red (hot) peppers, water mellon, carrots, pink grapefruit or extracts or mixtures thereof.
16. Process as claimed in claim 14-15, wherein the amount of carotenoid-containing fruit or vegetable are chosen such that the weight ratio of (plant) sterols or derivatives thereof : carotenoids in the final composition is between 100:1 and 10000:1.

**ABSTRACT**

5 The invention relates to an edible composition containing both (plant) sterols (and/or sterol-containing compounds) as well as carotenoids. Preferably the carotenoids are present in another phase than the (plant) sterols.

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